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427.056

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: : B. Fubara
LABARRE, et al. :
Serial No.: 10/089,287 : Group: 1615
Filed: March 26, 2002 :
For: CROSS-LINKED .. COPOLYMERS :
Hedman and Costigan
1185 Avenue of the Americas
New York, N.Y. 10036
August 2, 2005

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REAL PARTY IN INTEREST

The real party in interest in the present application is Societe De Conseils De Recherches Et D'Applications Scientifiques (S.C.R.A.S.), by means of an assignment from the inventors recorded at frame 0593 of Reel 012781.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant, the Appellants' legal representative or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF THE CLAIMS

The claims on appeal are claims 1 to 21 and 28 to 31, all other claims being cancelled.

STATUS OF THE AMENDMENTS

No amendment was filed to the Office action of March 7, 2005.

SUMMARY OF THE INVENTION

Applicant's invention is directed to a cross-linked copolymer prepared from a reaction between two separate non-cross-linked polycarboxylic copolymers and a cross-linking agent having at least two amine functions, each non-cross-linked polycarboxylic copolymer comprises at least one non-cross-linked polysaccharide linked by a covalent bond to at least one non-saccharidic non-cross-linked polymer, and where

at least one of the polysaccharides and of the non-saccharidic non-cross-linked polymers is polycarboxylic, as defined in Claim 1, a process for their preparation as set forth in Claim 19 and use thereof for treating colon diseases therewith as set forth in Claim 28.

ISSUES

Claims 1 to 18, 20, 21 and 28 to 31 have been rejected under 35 U.S.C. 102 as being anticipated by El et al. WO 98/08897 and Claim 19 was rejected as being obvious therefrom taken in view of Heidel et al. patent No. 5,219,971.

The Examiner states that El discloses cross-linked copolymers that are based on non cross-linked polycarboxylic polymers and cross-linking agent, which has at least two amine functions; the cross-linked copolymer comprises at least one polycarboxylic polysaccharide and at least one non cross-linked polycarboxylic polymer that is not a polycarboxylic polysaccharide (page 1, line 16 to page 2, line 5). The non cross-linked polycarboxylic polysaccharide is selected from glycosaminoglycan, pectinic acid (pectin), alginic acid, carboxymethyldextran, carboxymethylcellulose (page 2, lines 6-11 and 21-24) and these polysaccharides are not polycarboxylated. Non polysaccharide polycarboxylic polymers are selected from poly(glutamic acid), poly(aspartic acid), poly(acrylic acid), poly(methacrylic acid) and EUDRAGIT L and S (page 2, lines 11-15). Heidel is cited to show polymerization under a nitrogen atmosphere.

Claims 1 to 18, 20, 21 and 28 to 31 have been rejected under 35 U.S.C. 102(e) as being anticipated by the Lambert et al. patent No. 6,229,009 and Claims 1, 4 to 6, 9 to 12, 14, 17, 18, 20 and 21 as claiming the same invention as Lambert et al. Claim 13 was rejected on obvious double patenting over Lambert et al. The Examiner states that Lambert discloses cross-linked copolymer that is based on at least one non-crossed

linked polycarboxylic polysaccharide and at least one second non-cross linked polycarboxylic polymer that is not a polycarboxylic polysaccharide (abstract). The non-cross linked polysaccharide is selected from glycosaminoglycans, pectinic acid, alginic acid, carboxymethyldextran and carboxymethylcellulose (column 1, lines 49-56). The non-saccharide polycarboxylic polymer is selected from poly(glutamic acid), poly(aspartic acid), poly(acrylic acid), poly(methacrylic acid and EUDRAGIT L and S (column 1, lines 57-62).

With respect to claiming by the same inventor, the Examiner states that Claim 1 while worded slightly different claims the same invention as Lambert et al. since Claim 1 is a cross-linked copolymer prepared from a reaction between a cross-linking agent that has at least two amine functions and non-cross-linked polycarboxylic copolymer where the non-cross-linked polycarboxylic copolymer comprises at least one non-cross-linked polysaccharide and at least one non-saccharidic non-cross-linked polymer and where at least one of the non-saccharide non-cross-linked polymer is polycarboxylic.

GROUPING OF THE CLAIMS

All the claims start or fall together.

APPLICANTS' ARGUMENTS

Applicants respectfully traverse this ground of rejection since the El et al reference does not anticipate or render obvious Applicants' invention. As pointed out on page 1 in the application as filed, the El et reference uses a process which consists of mixing the polycarboxylic polymers of the two types, i.e. polysaccharidic and non-polysaccharidic in an aqueous solution but said process does not exclude a final cross-linked copolymer consisting of heterogeneities resulting with the cross-linking reactions between the polysaccharides only or between the non-polysaccharidic carboxylic polymers only. The present invention is intended to obviate this problem and to exclude the formation of heterogeneities. This problem is solved by first reacting the copolymers of the two starting types, namely, the polysaccharide polymer on the one hand and the non-saccharidic polymer (one being polycarboxylic) on the other hand to link the two by means of a covalent bond to form a non-cross-linked polycarboxylic copolymer and the non-cross-linked copolymer is then reacted with a cross-linking agent to form a cross-linked copolymer based upon the non-cross-linked polycarboxylic copolymers is distinct from the type of polymers obtained by the El et al reference. Therefore, the same does not anticipate or render obvious Applicants' invention and withdrawal of this ground of rejection is requested.

With respect to the Lambert et al patent rejection, this patent is the United States counterpart of the El patent and the same distinctions are applicable thereto. With respect

to the double patenting rejection, Claim 1 is not the same invention as claimed in Lambert but "the wording between the claims is slightly different". This is not correct since the Lambert et al suffers the deficiency noted above with respect et El and as noted on page 1 of the application.

CONCLUSION

It is believed that the claims clearly point out Applicants' invention to distinguish from the Prior art and Applicants have complied with all the requisitions for the granting of Letters Patent. Therefore, the Board of Appeals and Interferences is requested to reverse the Examiner's rejection. Three copies of the Brief are filed herewith as well as PTO form 2038 for \$500 for the fee for filing the brief.

Respectfully submitted,
Hedman and Costigan



Charles A. Muserlian

CAM:mlp
Enclosures



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	:	July 11, 2005

APPENDIX

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Claims in the Application are:

Claim 1 (currently amended)

A cross-linked copolymer prepared from a reaction between two separate non-cross-linked polycarboxylic copolymers and a cross-linking agent having at least two amine functions, each non-cross-linked polycarboxylic copolymer comprises at least one non-cross-linked polysaccharide linked by a covalent bond to at least one non-saccharidic non-cross-linked polymer, and where

at least one of the polysaccharides and of the non-saccharidic non-cross-linked polymers is polycarboxylic.

Claim 2 (previously presented)

A copolymer of claim 1, wherein the polysaccharide is non-polycarboxylic.

Claim 3 (previously presented)

A copolymer of claim 2 wherein the non-cross-linked non-polycarboxylic polysaccharide is selected from the group consisting of agarose, agaropectin, amylose, amylopectin, arabinogalactan, carrageenans, cellulose, methylcellulose, chitosan, dextran, keratan sulfate, fucans and fucoidans, tragacanth, arabic, locust bean, guar gums and pullulan.

Claim 4 (previously presented)

A copolymer of claim 1 wherein the polysaccharide is polycarboxylic.

Claim 5 (previously presented)

A copolymer of claim 4 wherein the polycarboxylic polysaccharide is selected from the group consisting of glycosaminoglycans, pectinic and alginic acid.

Claim 6 (previously presented)

A copolymer of claim 4 wherein the polycarboxylic polysaccharide is glycosaminoglycane selected from the group consisting of hyaluronic acid, chondroitin sulfate, heparin, dermatan sulfate and heparan sulfate.

Claim 7 (previously presented)

A copolymer of claim 1 wherein the non-saccharidic polymer is non-polycarboxylic.

Claim 8 (previously presented)

A copolymer of claim 7 wherein the non-polycarboxylic non-saccharidic polymer is selected from the group consisting of poly(vinyl acetate), poly(vinyl alcohol), poly(acrylic esters), poly(methacrylic esters), poly(methacrylamies) and poly(acrylamides).

Claim 9 (previously presented)

A copolymer of claim 1 wherein the non-saccharidic polymer is polycarboxylic.

Claim 10 (previously presented)

A copolymer of claim 9 wherein the non-saccharidic polymer is a polycarboxylic acrylic polymer.

Claim 11 (previously presented)

A copolymer of claim 10 wherein the polycarboxylic acrylic polymer is poly(acrylic acid) or poly(methacrylic acid).

Claim 12 (previously presented)

A copolymer of claim 1 wherein the cross-linking agent is selected from the group consisting of diamines, natural and synthetic amino acids and polyamides.

Claim 13 (previously presented)

A copolymer of claim 12 wherein the cross-linking agent is a diamine.

Claim 14 (previously presented)

A copolymer of claim 1 wherein the polysaccharide is degradable by the microbial flora of the colon.

Claim 15 (previously presented)

A copolymer of claim 14 wherein the polysaccharide is selected from the group consisting of chondroitin sulfate, hyaluronic acid, pectinic acid, heparin, dextran, chitosan, amylose, pectin, alginates and xanthan.

Claim 16 (previously presented)

A copolymer of claim 15 wherein the polysaccharide is chondroitin sulfate, the other said non-saccharidic polymer is poly(acrylic acid) or poly(methacrylic acid), and the cross-linking agent is hexanediamine.

Claim 17 (currently amended)

A process for the preparation of cross-linked copolymers of claim 1 comprising reacting said two separate non-cross-linked polycarboxylic copolymers in an aqueous medium in the presence of an activator of said cross-linking agent.

Claim 18 (previously presented)

The process of claim 17 wherein the activator is selected from the group consisting of carbodiimides, quinoline derivatives and mixed anhydrides.

Claim 19 (previously presented)

A process for the preparation of non-cross-linked copolymers of claim 1, comprising grafting the monomer of the non-saccharidic polymer onto the polysaccharide in an aqueous medium, under an inert atmosphere and in the presence of a catalyst, which monomer will then polymerize under these reaction conditions.

Claim 20 (previously presented)

A pharmaceutical composition containing at least one active ingredient and, as an inert support or excipient, at least one cross-linked copolymer of claim 1.

Claim 21 (previously presented)

A pharmaceutical composition containing at least one active ingredient and, as an inert support or excipient, at least one copolymer of claim 14.

Claims 22 to 27 (cancelled)

Claim 28 (previously presented)

A method of treating a disease of the colon in warm-blooded animals comprising administering to warm-blooded animals in need thereof an effective amount of an active colon treating ingredient with an excipient of at least one copolymer of claim 1 for sustained release.

Claim 29 (previously presented)

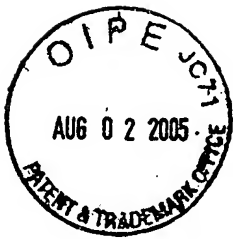
The method of claim 28 wherein the active ingredient is absorbed at the colon level.

Claim 30 (previously presented)

The method of claim 30 wherein the active ingredient is released in the upper parts of the digestive tract.

Claim 31 (previously presented)

A cross-linked copolymer prepared from a reaction between at least one non-crossed-linked polysaccharide and at least one non-polysaccharide non-cross-linked polymer to link the two by a covalent bond to form a non-cross-linked polycarboxylic copolymer and reacting the latter with a cross-linking agent to form a cross-linked copolymer, at least one of the polysaccharides or non-cross-linked polymer being polycarboxylic.



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I hereby certify that this correspondence is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" Service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

Marie-Louise Pinset
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